Aiscenovica Oral and Surface Drug Test Kit

Non-medical Use. Ref. no: SSCA-8003
AMP/BZO/COC/FEN/MET/MOR/MTD/OXY

Aiscenovica Oral and Surface Drug Test Kit is for qualitative detection of 8 commonly abused drugs and drug metabolites including **Amphetamine, Benzodiazepines, Cocaine, Fentanyl, Methamphetamine, Morphine, Methadone and Oxycodone** drug residue in human **oral fluid** or **drug residue trace on surfaces**.

Test	Calibrator	Cutoff (ng/mL)
AMP	d-Amphetamine	50 ng/ml
BZO	Oxazepam	10 ng/ml
COC	Benzoylecgonine	20 ng/ml
FEN	Fentanyl	2 ng/ml
MET	d-Methamphetamine	50 ng/ml
MOR	Morphine	10 ng/ml
MTD	Methadone	30 ng/ml
OXY	Oxycodone	40 ng/ml

Warnings:
Aiscenovica Oral and Surface Drug Test Kit provides only preliminary drug test results. It is designed as a rapid onsite screening tool for drugs of abuse. To confirm any test result, a more specific method such as Chromatography Mass Spectrometry (GC-MS/MS or LC-MS/MS) should be used. Preliminary results from this kit must not be used solely as legal evidence without confirmatory laboratory analysis. If evidentiary use is intended, a professional collection kit should be used and the sample submitted to a certified laboratory for confirmatory analysis.

Aiscenovica Oral and Surface Drug Test Kit is to be used for forensic or research use only and not for medical diagnostic purposes. The test is intended to be administered by trained professionals.

Rapid qualitative testing are intended to provide clients with fast, timely on-site screening or safety warnings. If you are involved in a legal dispute or intend to use the test results in legal proceedings against another party, we recommend that, following a positive result from rapid or on-site qualitative testing, you collect samples and submit them to a fully accredited laboratory for quantitative confirmatory analysis, such as LC-MS/MS or GC-MS/MS testing. We strongly recommend that you consult your attorney to obtain complete and reliable legal advice.

It is not recommended to rely solely on rapid testing or qualitative test results as legal evidence in court. We shall not be liable for, and expressly disclaim, any claims or losses arising from a customer's sole reliance on rapid testing results as legal evidence.

Technology and Explanation

AMP: Amphetamine is a potent sympathomimetic amine structurally related to natural catecholamines such as epinephrine and norepinephrine.

BZO: Benzodiazepines are a class of psychoactive substances with sedative and hypnotic effects. They may be detectable in oral fluid for up to approximately 24 hours after use.

COC: Cocaine is a powerful central nervous system stimulant derived from the coca plant. It works by blocking the reuptake of neurotransmitters such as dopamine, norepinephrine, and serotonin, leading to increased levels in the brain. This results in heightened alertness, energy, and euphoria.

FEN: Fentanyl is an extremely fast acting synthetic opioid related to the phenylpiperidines, a potent narcotic analgesic with short duration of action. It binds to opioid receptors in the brain and may produce effects such as pain relief and euphoria.

MET: Methamphetamine is a potent sympathomimetic agent with therapeutic applications. Methamphetamine use in acute higher doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, and a sense of increased energy and power.

MOR: Heroin, morphine, and codeine are opiates that are derived from the resin of the opium poppy. Heroin is quickly metabolized to 6-acetyl morphine and morphine. They act on opioid receptors in the brain and may produce effects such as pain relief and euphoria.

MTD: Methadone is a long-acting opioid used in the treatment of opioid addiction and chronic pain management. It works by binding to the same opioid receptors in the brain as other opioids, but it does so in a way that reduces cravings and withdrawal symptoms without producing the same high.

OXY: Oxycodone is a semi-synthetic opioid that acts on the central nervous system to alter the perception of pain. It may also produce euphoria and has a potential for misuse.
For more information, please refer to the Specificity section, which lists structurally related compounds that may produce a positive result.

Aiscenovica Oral and Surface Drug Test Kit is designed for rapid and user-friendly onsite screening, delivering results in approximately 5-10 minutes. The device can be used for the detection of drug residues (Trace Amount) on contaminated solid surfaces or in powder form, without the need for liquid handling or additional sample preparation.

It is also available in a format for oral fluid testing, where sample collection is performed directly according to the provided instructions, with no pretreatment required. It allows repeated and convenient sampling without the need for urine specimens, making it suitable for quick screening in various settings.

Aiscenovica Oral and Surface Drug Test Kit is based on competitive lateral flow immunoassay to qualitatively detect illicit drugs and their metabolites. Drug antibodies were conjugated to colloidal gold nanoparticles. After samples are applied, the nanoparticle-antibody conjugate will flow and bind to the drug conjugate line located on the nitrocellulose membrane of the test strip forming a red color line for each drug target. If the sample contains drug, the drug molecule will competitively bind to the antibody on the gold nanoparticles. The antibody-gold conjugate nanoparticles will not bind the drug conjugate on the membrane and therefore no colored line will be formed (positive).

Precautions

- For Forensic Use only.
- The test device is for single use and should remain in its original sealed pouch until ready for use.
- Do not use after the expiration date indicated on the kit.
- Handle all oral specimens as potentially infectious. The used device should be discarded according to federal, state and local regulation. Follow universal precautions when handling specimen and use safe laboratory procedures outlined in Biosafety in Microbiological and Biomedical Laboratories (HHS Publication Number [CDC] 93- 8395).

Materials Provided

5 Test Kits packaged individually in a foil pouch and 1 manual.

Storage and Stability

1. Store at 2°C-30°C. Do not open pouch until ready to perform the assay.
2. Keep away from direct sunlight, moisture and heat.

Test Procedure

For Oral Fluid:

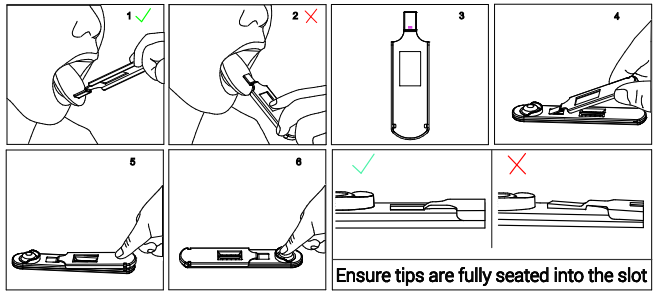
Allow the test device to reach room temperature 15-30°C, and instruct the donor not to eat, drink, smoke or chew tobacco products for at least 15 minutes prior to collection of fluid specimen.

1. Remove the test device and the flocked pad from the sealed pouch and use the device as soon as possible.
2. Wipe saliva on the tongue with the pad tip (Picture 1). Do not rub the whole pad against tongue, this may not collect enough saliva sample (Picture 2). The collection is finished when a pink spot indicator appears (Picture 3). About 80uL saliva is collected.
3. Insert the flocked pad in the device (Picture 4).
4. Press until double click to lock (Picture 5).
5. Lay the device on a flat surface and press the reagent blister by thumb until the blister collapses completely to release all the buffer (Picture 6).
6. When the liquid sample appears to wick/migrate along both of the strips, start the timer. Read results between 5 to 10 minutes. The results are invalid after 10 minutes.

After releasing the buffer solution, be sure to keep the test panel flat to avoid flooding the test strip.

When wiping the flocked pad in mouth for oral fluid collection, the user must not chew or swallow any part of the pad. Oral fluid will be absorbed into the pad head by capillary force. Do not place the flocked pad in mouth for extended time (more than 1 minutes).

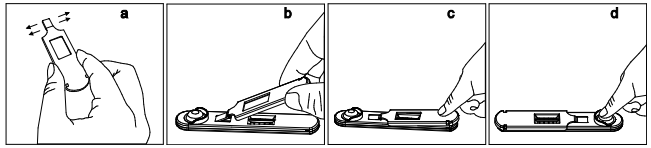
Under certain physiological or pathological conditions, such as waking up from sleep in the early morning, dry mouth syndrome, oral fluid collection time may be prolonged.



For Drug Residue

1. Remove the test device and the flocked pad from the sealed pouch and use the device as soon as possible.
2. Wipe the suspected surfaces (about 10cm * 10cm, sample loading should be less than 500ug) or swab on different areas with the flocked pad back and forth (Picture a).
3. Insert the flocked pad in the device (Picture b).
4. Press until click to lock (Picture c).
5. Lay the device on a flat surface and press the reagent blister by thumb until the blister collapses completely to release all the buffer (Picture d).
6. When the liquid sample appears to wick/migrate along both of the strips, start the timer. Read results between 5 to 10 minutes. The results are invalid after 10 minutes.

After releasing the buffer solution, be sure to keep the test panel flat to avoid flooding the test strip.



Interpreting Test Results

Negative Results

A red colored band should be observed in control region (C), and specific drug test region. The color and density of the test band may vary for control and drug test region. Do NOT compare the color of the T line with the color of the C line.

Presumptive Positive Results

When the control band is visible in the control region (C) and no band appears at the specific test region, the result is a **presumptive positive** for that particular drug.

Invalid

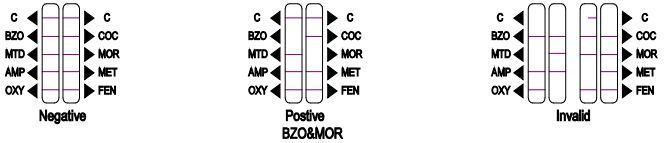
When **no** band appears in the control (C) region, **the test is invalid** regardless of the results in the test region. If the test is invalid, check testing procedures. **Repeat the test using a new device.**

Innovative Feature of the Control Line (C-Line):

We have introduced an innovative functional improvement to the Control Line (C-Line). Under certain conditions-such as when the sample contains high concentrations of salt ions-the C-Line will disappear. This design serves as a built-in warning mechanism, alerting the user that the collected sample is either excessive (overloaded) or contains interfering substances that prevent the test strip from functioning normally. If the C-Line disappears, the test result is invalid and must not be read. In such cases, you should readjust the sample volume or employ alternative testing methods.

Disclaimer:

Based on the intentional design purpose of the feature described above, we shall not be held liable for any compensation, replacement, or reissue of test panels due to the disappearance of the C-Line.



Important: Do not compare color intensity of one test band to another. Read each test independently.
Any darker or light red band for a specific test is observed in the test region along with the presence of the control line (C), the sample should be considered Negative. However, in case a faint test line appears, it is recommended to repeat the test. For confirmation of a presumptive positive result, a more specific quantitative method (LC-MS/MS or GC-MS/MS) must be used.

Quality Control and Cut-off Determination

The quality control standards and analytical cut-off levels for this drug trace test panel are established and calibrated using standard matrix-matched control solutions. In alignment with established industry conventions, the threshold performance is validated at -50% below the cut-off level for negative controls and +50% above the cut-off level for positive controls.

Although all **Aiscenovica Oral and Surface Drug Test Kit** lots undergo strict quality surveillance and control, it is recommended that the product user perform quality control with known negative and positive samples at a regular basis. Quality control test is also recommended when a new lot is going to be used or the product has been stored outside of the recommended storage conditions. Negative and positive controls should give the expected results when tested by pipetting 80 uL of the controls onto the flocked pad.

Test Limitations

Rare false positive or false negative results may occur due to non-specific cross reaction between the test reagent in the test strip and certain component in the oral fluid. The cause of the false results could be from a food component that contains compounds with similar or identical structure for binding to the test reagent. Other conditions such as physiological or pathological conditions, or the donor taking medicine, could also produce false results. If the test result is suspicious, further confirmation testing using GC-MS/MS or LC-MS/MS method is recommended.

The assay is designed for detection of nano scale drug residues. Positive results only indicate the presumptive presence of drugs. It is not intended to test ″anything and everything″(sodas/alcohols, food products, household chemicals, phytosanitary products, cosmetics), which may contain chemical or biological compounds that could interfere with the proper functioning of the test.

This assay uses antigen-antibody reactions. Its core reaction depends on the biological activity of antigen-antibody interactions. If the test sample is in an extreme physicochemical environment such as high salt concentration, strong acids, strong alkalis, alcohols, ketones, or aldehydes, it will directly disrupt the spatial structure and biological activity of the antigen-antibody system on the test strip. This will lead to inactivation of the reagent system, resulting in test failure or abnormal results.

Do not overload the sample. Do not collect visually detectable amounts of sample, including but not limited to powders and liquids. A trace amount is sufficient. Overload will cause malfunction!
Do not collect viscous samples, so as to avoid clogging of the assay strip.

Specificity

The specificity of each drug test was evaluated by adding its structurally related compounds to pooled oral fluid sample. The results are expressed as the lowest concentration of the compound in ng/ml that produced a positive result. This is not a complete list of all substances that may potentially cause a positive reaction on the test strip.

Drug Test	Approximate Concentration(ng/ml)
Amphetamine (AMP)	
d-Amphetamine	25
l-Amphetamine	1,000
d,l-p-Chloramphetamine	200
MDA	200
Phentermine	50
β-Phenylethylamine	5,000
Tyramine	5000
Benzodiazepine (BZO)	
Oxazepam	10
Alprazolan	20
a-Hydroxyaprazolan	100
Bromazepam	20
Clobazam	10
Clonazepam	400
Delorazepam	25
Chlordiazepoxide	500
Cocaine (COC)	
Cocaine	20
Benzoylecgonine	**20**
Ecgonine HCl	800
Ecgonine methylester	200
Fentanyl(FEN)	
Fentanyl	2
Norfentanyl	10
Methamphetamine (MET)	
d-Methamphetamine	25
d,l-Ephedrine	5000
1R, 2S l-Ephedrine	3000
p-Hydroxymethamphetamine	1000
MDEA	1000
MDMA	75
d,l-Methamphetamine	50
l-Methamphetamine	750
Methoxyphenamine	5000
Methadone(MTD)	
Methadone	30
Hydrocodone	10000
Morphine	>100,000
Hydromorphone	>100,000
Opiates (OPI)	
Morphine	**10**
6-Acetylcodeine	40
6-Acetylmorphine	100
Codeine	75
Dihydrocodeine	250
Ethyl morphine	100
Heroin	50
Hydrocodone	250
Hydromophone	400
Oxycodone(OXY)	
Oxycodone	40
Hydrocodone	10000
Morphine	>100,000
Hydromorphone	>100,000

Interference

The **Aiscenovica Oral and Surface Drug Test Kit** performance at ±50% cut-off levels is not affected by oral fluid samples with pH range of 2.0 to 8.5. The following compounds were tested no interfering with assay performance when tested at concentration of 10 µg/ml (10,000ng/ml).

Acetaminophen	Hemoglobin
Albumin from human serum	Human IgA
l-Ascorbic Acid	Human IgG
Aspartame	Human IgM
Benzocaine	Ibuprofen
Benzoic acid	Ketamine
Bilirubin	Lidocaine
Caffeine	Naloxone
d-Chlorpheniramine	Naltrexone hydrochloride
Cholesterol	d-Naproxen
Dextromethorphan	Pentazocine
Diphenhydramine	Promazine
Doxylamine	Promethazine
1R, 2S l- Ephedrine *(except MET assay)*	Ranitidine
1S, 2R d-Ephedrine	Riboflavin
l-Epinephrine	Salicylic acid
Erythromycin	Serotonin
Ethanol	Tetracycline
Glutethimide	Thiamine

Food/Beverage/Hygiene Products Interference

Foods, drinks and hygiene products were spiked at 1% concentration in ±50% oral fluid controls to evaluate the interference with **Aiscenovica Oral and Surface Drug Test Kit** test results. For interference of cigarette, oral fluid samples were collected from 6 subjects within 15 minutes after consuming a cigarette and then spiked with drug standards.

The following substances were found not to interfere with **Aiscenovica Oral and Surface Drug Test Kit**.

Mouth Wash	Orange Juice	Alcohol
MSG	Apple Juice	Tea
Toothpaste	Food color: Red	Carbonated Cola
Gum	Food color: Green	Baking Soda
Coffee	Food color: Blue	Cigarette
Cough Syrup	Sugar	Salt

REFERENCES

1. Schramm, W; SmithRH, et al. Drugs of Abusein Oral fluid: A Review. J. Anal. Toxicol. 16, 1992, 1-9.
2. Edward JC and Marilyn AH. Interpretation of Oral Fluid Tests for Drugs of Abuse. Ann. N.Y. Acad.Sci., 3, 2007, 1098: 51-103.
3. Caplan, YH; Goldberger BA. Alternative Specimens for Workplace Drug Testing. J. Anal. Toxicol. 25, 2001, 396-399.
4. Wolff, K; Farrell, M, et al. A Review of Biological Indicators of Illicit Drug Use, Practical Considerations and Clinical Usefulness. Addiction, 94, 1999, 1279-1298.
5. Schwarzhoff, R and Cody, JT. The Effects of Adulterating Agents on FPIA Analysis of Urine for Drug of Abuse. J. Anal. Toxicol. 17, 1993, 14-17.
6. O"Neal, CL; Crouch, DJ, etal. Correlation of Oral fluid Codeine Concentrations with Plasma Concentration after Oral Codeine Administration. J. Anal. Toxicol. 23, 1999, 452-549.
7. Jenkins, AJ; Oyler, JM, etal. Comparison of Heroine and Coceine Concentrations in Oral fluid with Concentrations in Blood and Plasma. J. Anal. Toxicol. 19, 1995, 359-374.
8. Lindsay, FH. Human Oral fluid as a Diagnostic Specimen. J. Nutri.131, 2001,1621s-1645s.
9. Eliaz, K and Ira, BL. The Diagnostic Applications of Oral fluid – A Review. Crit. Rev. Oral Biol. Med. 13(2), 2002,197-212.

Glossary of Symbols

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
	Use by		Contains sufficient for <n> tests
	Do not reuse	EC REP	Authorized representative in the European Community
CE	CE marking		

Manufactured for:
Scenesafe Inc.
Halifax and Truro, Nova Scotia, Canada
Website: www.scenesafe.ca
Email: Halifax@scenesafe.ca

Made in China with globally sourced materials